

**Remarks/Arguments:**

Applicants wish to thank Examiner Jane J. Zara for acknowledging receipt of the certified copy of the priority document and, accordingly, for granting foreign priority under 35 USC 119.

Claims 1 and 10, currently amended, and claims 2-4, 6-9, and 11, previously presented, are pending.

Claims 5, 12, and 13 are canceled, without prejudice or disclaimer.

Claim 6 is withdrawn, pursuant to restriction.

Claims 1 is amended, hereby, in order to incorporate claims 3-5. Claims 1 and 10 are amended, hereby, and in order to more clearly define the invention as described in the specification (page 8, ¶3)—to clarify that the oligonucleotide can have one or more modifications that are conventional in oligonucleotide chemistry—see, for example, Eurogentec, online at \*\* (a copy of which is attached, hereto, for the examiner's convenience). Claim 10 is, also, amended to more clearly define the instant invention—by using the identical language of the antecedent basis found in amended claim 1.

Claims 1-4, 7, 8, 12, and 13 were rejected under 35 USC 102(b) as being allegedly anticipated by *PNAS*, 93, 1996, 2909-2914 (Fakhrai). Reconsideration of the rejection is requested.

First of all, as applied against claims 4, 12, and 13 the rejection is rendered moot, since claims 4, 12, and 13 are cancelled, hereby.

Secondly, by the instant amendment, applicants have limited the (pending) rejected claims, *i.a.*, to the subject matter of claim 5. Since claim 5 was not rejected based on Fakhrai, the instant

amendment effectively renders the rejection moot. As such, withdrawal of the rejection under §102(b) based on Fakhrai appears to be in order.

Claims 1-4, 7, 8, and 9 were rejected under 35 USC 102(e) based on US 6,376,199 (Caniggia). Reconsideration is requested.

First of all, as applied against claims 4, the rejection is rendered moot, since claim is cancelled, hereby.

Secondly, as explained in the previously filed amendment, Caniggia is not available as prior art against the subject application under §102(e). The §102(e) date of the reference is December 21, 1999, which is antedated by the filing date of the subject, National Stage application—June 10, 1999.

Nevertheless, in order to advance prosecution, applicants have limited the rejected claims, hereby, to the subject matter of claim 5. Since claim 5 was not rejected based on Caniggia, the instant amendment effectively renders the rejection moot. As such, withdrawal of the rejection under §102(e) based on Caniggia appears to be in order.

The objection to claim 8 cannot be understood. According to the objection, "interleukins"—appearing at line 5 of the claim—is allegedly a "misspelling" (Office Action, page 4). The allegation appears to be incorrect. For the examiner's convenience, the cover page of United States Patent 5,919,898—entitled "Absorbent for Removing Interleukins and Tumor Necrosis Factor, and Process for Removing the Same" (emphasis added)—is attached hereto.

Claims 1-5 and 7-11 were rejected under 35 USC 112, 1<sup>st</sup> ¶, for allegedly failing to comply with the written description requirement. Reconsideration of the rejection is requested.

First of all, as applied against claims 4, 5, and 11, the rejection is rendered moot, since claims 4, 5, and 11 are cancelled, hereby.

Secondly, the statement of rejection alleges that the subject application does not provide sufficient descriptive support for the genera "inhibitor of the effect of a substance negatively effecting an immune response" and "stimulator positively effecting an immune response." In accordance with the instant amendment, the "inhibitor" genus is, now, limited to one of the oligonucleotides "of SEQ ID NOS: 1-213," optionally having one or more modifications that are conventional in oligonucleotide chemistry (as explained, above). Thus, the genus of "at least one inhibitor of the effect of a substance negatively effecting an immune response," as recited in the present (amended) claims, literally covers only the 213 oligonucleotide species expressly disclosed in the subject application, and those modifications, thereof, disclosed in the subject application, which are conventional in oligonucleotide chemistry. One of ordinary skill in the art would have, accordingly, readily appreciated all of the species that fall within the "inhibitor" genus "oligonucleotide" of the presently claimed invention (claims 10 and 11) and the oligonucleotide component of the presently claimed medicament (claims 1, 2, 7, 8, and 9).

With respect to the "stimulator" genus (component) of the presently claimed medicament, the present specification dedicates three complete pages (pages 3-5) to describing species within the claimed genus. While the statement of rejection (Office Action, page 6) alleges "One of skill in the

art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the . . . [inhibitor genus] claimed," it fails to explain *how* the three pages of text in the specification that are dedicated to describing species of the genus "fails to provide a representative number of species."

Moreover, medicament stimulators useful in accordance with the presently claimed invention include those well known in the art. Such well known stimulators need not be specifically identified in the subject application in order to satisfy the written description requirement of § 112, ¶1. In order to satisfy the requirements of § 112, first paragraph, "it is not necessary to embrace in the claims or describe in the specification all possible forms in which the claimed principle may be reduced to practice." *Smith v. Snow*, 294 U.S. 1, 11 (1935). The law does not require an applicant to describe in his specification every conceivable embodiment of the invention. *SRI Int'l v. Matsushita Elec. Corp. of America*, 227 USPQ 577, 586 (Fed. Cir. 1985).

For the foregoing reasons, both of the "inhibitor" and "stimulator" genera are supported by sufficient descriptive text in the present specification to satisfy the written description requirement of § 112, ¶1. Accordingly, the rejection under § 112, ¶1, for alleged failure to satisfy the written description requirement appears to be in order for withdrawal.

Claims 1-5 and 7-11 were rejected under 35 USC 112, 1<sup>st</sup> ¶, for allegedly lacking enablement. Reconsideration of the rejection is requested.

First of all, as applied against claims 4, 5, and 11, the rejection is rendered moot, since claims 4, 5, and 11 are cancelled, hereby.

Secondly, in order to sustain a rejection for lack of enablement, and shift the burden to a patent applicant, the PTO must cite evidence in support of any allegations of non-enablement, in addition to explaining *why* it doubts the truth of statements of enablement made in the specification. *In re Sichert*, 196 USPQ 209 (CCPA 1977). Lack of enablement is not demonstrated merely because the claim scope might, theoretically, cover embodiments that do not work; the function of the claims is not to specifically exclude possibly inoperative embodiments. *Atlas Powder v. E.I. du Pont de Nemours Co.*, 224 USPQ 409 (Fed. Cir. 1984). Even in an unpredictable area, such as chemistry, the PTO must advance reasons why a patent applicant's broad assertion of enablement is not true. *In re Bowen*, 181 USPQ 48 (CCPA 1974). Lack of enablement under §112 is not established by mere allegations of undue breadth, that is, by merely arguing that claims read on non-disclosed embodiments. *Horton v. Stevens*, 7 USPQ2d 1245 (BPA & I 1988). While working examples drawn to specific embodiments may be desirable, they are not *required* in order to satisfy enablement under §112. *In re Strahilevitz*, 212 USPQ 561 (CCPA 1982). It is well established that working examples are not necessary when one possessed of knowledge of ordinary skill in the art could practice the invention without the exercise of undue experimentation. *Ex parte Nardi*, 229 USPQ 79 (BPA & I 1986). "In satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art." *Staehelin v. Secher*, 24 USPQ2d 1513, 1516 (BPA & I 1992).

As an initial matter, it must be remembered that the claims at issue define a composition of matter—a "medicament" (claims 1, 2, and 6-9) and the "oligonucleotide" component of the

medicament, itself (claim 10). Accordingly, while the "medicament" and the "oligonucleotide" are useful in the treatment of neoplasms, the claims at issue are not *treatment*, i.e., method, claims.

According to the statement of rejection, the rejection is based, *i.a.*, on the allegation "Applicants have not provided guidance in the specification toward a method of treating *any* neoplasm" (Office Action, page 9, *emphasis added*). In other words, satisfaction of enablement under §112, ¶1, (according to the statement of rejection) that the present specification must enable the treatment of *any* neoplasm. In this respect, the statement of rejection is mistaken.

Enablement under §112, ¶1, is satisfied for using the claimed invention when the "claimed invention meets at least one . . . objective" stated in the specification. *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1094, 1100 (Fed. Cir. 1991). "An invention . . . need only be useful to some extent and in certain applications." *Id.* Total incapacity, i.e., incapacity with respect to all uses of the invention described in the specification, is necessary to demonstrate lack of enablement with respect to the invention claimed. *Tol-O-Matic Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H.*, 20 USPQ2d 1332, 1338 (Fed. Cir. 1991).

The statement of rejection admits that enablement is satisfied for at least one stated objective—"for treating a brain neoplasia" (Office Action, page 7). Accordingly, the statement of rejection implicitly acknowledges that enablement is satisfied for the presently claimed invention. *Carl Zeiss Stiftung, supra*. Withdrawal of the rejection under §112, ¶1, for alleged lack of enablement, appears to be in order.

Claims 1-5, 7, 8, 10, and 11 were rejected under 35 USC 102(a) as being allegedly anticipated by WO98/33904. Reconsideration of the rejection is requested.

First of all, as applied against claims 4, 5, and 11, the rejection is rendered moot, since claims 4, 5, and 11 are cancelled, hereby.

Secondly, WO98/33904 has an effective date as prior art, under §102(a), of 6 August 1998—its publication date. The rejected claims are entitled to a priority date under §119(a) no later than 25 July 1998, i.e., the filing date of EP98113974.4. Since WO98/33904 does not have an effective date as prior art before the priority date for the rejected claims, the rejection cannot be maintained. Withdrawal of the rejection under §102(a) based on WO98/33904 appears to be in order.

Claims 1-5, 7, 8, 10, and 11 were provisionally rejected under 35 USC 101 as allegedly claiming the same invention as claims 12-15 in US10/984,919. Reconsideration of the rejection is requested.

First of all, as applied against claims 4, 5, and 11, the rejection is rendered moot, since claims 4, 5, and 11 are cancelled, hereby.

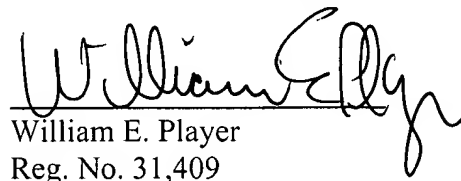
Secondly, the rejection is provisional. It only applies if and when claims 12-15—in the form relied on to support the rejection—are patented. Accordingly, the rejection is premature, since the claims relied on might never issue in a patent. Until the rejection is no longer provisional, no further reply is necessary.

Favorable action is requested.

Respectfully submitted,

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